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April 5, 2002

Felicia B. Satchell, Ph.D.
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration (HFS-820)
5100 Paint Branch Parkway
College Park, MD 20740-3835

RE: Docket No. 95S-0316;NEW DIETARY INGREDIENT NOTIFICATION - HiDHA® tuna oil

Dear Dr. Satchell:

This is a New Dietary Ingredient Notification by Clover Corporation Ltd. (Clover) for HiDHA® tuna oil for use in dietary supplements. Clover has also submitted a GRAS notification for HiDHA® tuna oil for food use (GRAS No. 97) which is pending before the Division of Bioltech and GRAS Notice Review. The contact person there with respect to this submission is Michael Watson, Ph.D. With respect to this notification, please make any requests for further information to Messrs. Drummond and Young at the e-mail addresses set forth below and we will respond as promptly as possible.

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1. Summary

This new dietary ingredient notification is submitted to the Food and Drug Administration (FDA) pursuant to Section 8 of the Dietary Supplement Health and Education Act of 1994 (21 U.S.C. § 350b) and 21 C.F.R. §190.6 with respect to the use of HiDHA® tuna oil as an ingredient for use in dietary supplements.

An Expert Panel convened to review HiDHA® tuna oil reported on October 18, 2000 on

> **The "GRAS" status of HiDHA® (docosahexaenoic acid) tuna oil products intended for use in place of menhaden oil in traditional foods per 21 C.F.R. 184.1472(a)(3), and in dietary supplements providing up to 1 gm HiDHA® tuna oil/day.**

The Expert Panel unanimously concluded that

> **"under the conditions of intended use in place of menhaden oil in conventional foods per 21 C.F.R. 184.1472(a)(3), and in dietary supplements of up to 1 gm/day, the HiDHA® tuna oil product, meeting appropriate food grade specifications and manufactured in accordance with current good manufacturing practices, are "generally recognized as safe" ("GRAS") based on scientific procedures."**

The full Export Panel Report is attached as Appendix I.

Clover Corporation, is the company that is the manufacturer and distributor of the new dietary ingredient, HiDHA® tuna oil.

2. Description of HiDHA® tuna oil

i) Chemistry

Fish oils are, by their very nature, complex materials consisting of a complex mix of glycerides, fatty acids, unsaponifiables and phospholipids. The CAS registry number for fish oils is 8016-13-5. This number is used for fish oils such as tuna oil, which do not have a unique CAS number. As stated in the Expert Panel Report (Appendix I, page 2):

> "As in the case of other food lipids, fish oils consist mainly of a mixture of triglycerides of various long chain fatty acids with small amounts of mono and diglycerides. The fatty acids that characterize fish oils are similar to those in the various edible vegetable oils and animal fats differing principally in their relatively higher proportion of polyunsaturated fatty acids with five and six double bonds, and tuna oil differs from other fish oils in the ratio of the C20:5 n-3 (EPA) to the C22:6 n-3 (DHA) fatty acids...".

Note that the ratio of EPA:DHA in tuna oil (around 1:4) is similar to that of human breast milk.

Table 1: Fatty Acid Composition of Tuna and Menhaden Oils

FATTY ACID	TUNA	MENHADEN
14:0	3.0	9.0
16:0	20.0	19.0
18:0	6.0	3.0
16:1	4.5	12.0
18:1	15.0	13.0
22:1	1.0	-
18:2	1.5	1.0
18:3	1.0	1.0
20:5	6.0	14.0
22:6	26.5	8.0

Reference: Expert Panel Report Appendix I, page 2

ii) Specifications

The HiDHA® tuna oil can be produced in a number of forms all of which are derived from the same raw tuna oil material and are processed in the same plant using essentially the same process route. The only differences are the degree of bleaching (number of bleach cycles) and winterization (the temperature of crystallization) employed during processing.

Table 2: Specifications for HiDHA® tuna oil products

Specification	HiDHA® Tuna Oil	HiDHA® Tuna Oil Powders	HiDHA® Tuna Oil Emulsions
Appearance	Pale yellow oil	White to light beige powder	Light beige emulsion
Odour	Faint fresh fish	Bland	bland
%Total Fat	100%	24-30%	25% min
Fatty Acid Profile*:			
Docosahexaenoic Acid (DHA), %*	25-28%	18-25%	25-28%
Eicosapentaenoic Acid (EPA), %*	5-8%	4-8%	5-8%
Total omega-3 fatty acid content, %*	32-40%	26-34%	32-40%
Acid Value, mgKOH/g	1.0	**	**

Peroxide Value, meq 0_2/kg	5	**	**
p-Anisidine Value	20	**	**
Colour, Gardner	4	**	**
Unsaponifiable Matter, %	2	**	**
Lead, ppm	0.1	**	**
Mercury, ppm	0.1	**	**
Cadmium, ppm	0.1	**	**
Arsenic, ppm	0.1	**	**
Total Heavy Metals, ppm	2	**	**
DDT, ppm	0.05	**	**
DDE, ppm	0.05	**	**
HCB, ppm	0.05	**	**
PCB, ppm	0.1	**	**
Lindane, ppm	0.05	**	**
Yeast and Mould (cfu/g)	<100		
Standard Aerobic Plate Count (cfu/g)	<100	<1000	<1000
Enterobacteriaceae (cfu/g)	<100		
E. coli	ND in 1g		
Salmonella spp.	ND in 10g	ND in 25g	ND in 25g
Coliforms (37°C)		ND in 0.1g	ND in 0.1g
Coagulase positive staph.		ND in 0.01g	ND in 0.01g
Baccillus cereus		ND in 0.01g	ND in 0.01g

* Fatty acid composition is expressed as a percentage of fatty acid methyl esters prepared for GC analysis [% area method]

** The fat content of these products (HiDHA® Tuna Oil Powders and HiDHA® Tuna Oil Emulsions) have the same values as those listed in column 2 of the Table.

Data sheets for the products presently available are included in Appendix II.

iii) Manufacturing

HiDHA® tuna oil is manufactured from raw tuna oil, a by-product of the edible tuna canning industry in American Samoa. Selected tuna fish are responsibly fished in the Southern Pacific Ocean using dolphin friendly methods. The Southern Pacific Ocean provides a sustainable catch of fish from a pollution-free environment. Tuna found in these waters have higher levels of DHA compared to tuna of other oceans. Harvested species include skipjack (*Katsuwonus pelamis*), yellowfin (*Thunnus albacares*), albacore (*Thunnus alulunga*), and bigeye (*Thunnus obesus*). All of these species have been widely consumed throughout history by humans. The tuna stocks are under no threat and the existing level of harvesting is sustainable.

Tuna are caught by high speed fishing vessels and are immediately blast frozen to below -35° C and kept at that temperature until the vessel arrives at the cannery. The tuna are removed from the cold storage and allowed to partially thaw to -5° C before further processing. The head is then removed and used for the production of raw tuna oil. Oil from the processing of the heads is not mixed with oil from the processing of the viscera, which occurs in a separate processing plant.

The liquid stream (presswater) generated in the short residence time cooker is separated from fine solids in a decanter centrifuge and the raw tuna oil is separated from the aqueous phase with a separator centrifuge. The oil is then treated with a citric acid solution to chelate pro-oxidant metal ions. The moisture in the raw tuna oil is less than 0.20% and most of the metal ions capable of initiating oxidation of the oil are removed along with the aqueous phase in this step of the process.

The raw tuna oil is then pumped into a stainless steel storage tank and cooled to ambient temperature while being continuously purged with food grade nitrogen, At the end of the production day, the raw tuna oil is pumped into containers that have been purged with nitrogen and are sealed after filling with oil under a nitrogen blanket.

The stabilized raw tuna oil is imported to Australia where it is refined to ensure the final product is stable and consistent to strict specifications.

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Table 3: Specifications for raw tuna oil

Specification	Limits
Product name	Stabilized Crude Tuna Fish Oil
Description	Dark brown, free flowing liquid
Docosahexaenoic acid (DHA), %	23.5% min
Eicosapentaenoic acid (EPA), %	5% min
Total omega-3 fatty acids	32.0% min
Iodine value	175 min
Moisture and impurities, %	1.0% max
Unsaponifiable matter, %	2.0% max
Free fatty acids, %	5.0% max
Anisidine number	240 max
Cholesterol, mg/g	22 max
Vitamin A (retinol), I.U./ml	500 max
Vitamin D3, I.U./ml	700 max
Arsenic, ppm	0.10 max
Cadmium, ppm	0.10 max
Copper, ppm	0.50 max
Lead, ppm	0.50 max
Mercury, ppm	0.10 max
PCBs, ppm	0.01 max
DDT/DDE, ppm	0.05 max
HCB, ppm	0.05 max
Lindane, ppm	0.05 max

The refining process includes the application of all or some of the accepted food processing techniques of winterization, degumming, neutralization, bleaching and deodorization, as appropriate, to provide oils that may be used for foods. The tuna oil refining plant was designed specifically for refining tuna oil and uses unit processes that are standard in the edible oil industry. The factory is licensed by the Australian Therapeutic Goods Administration and operates in accordance with pharmaceutical standard Good Manufacturing Practices (GMPs). The premises and the manufacturing processes have qualified for ISO 9002 and AQIS certification, and are operated to comply with a strict environmental protection code.

The Expert Panel Report (Appendix I, pages 10-17) provides full details on the manufacturing process in American Samoa and Australia for HiDHA® tuna oil and a range of products based on HiDHA® tuna oil.

iv) Analytical data

Detailed analytical data is provided in the Expert Panel Report (Appendix I, pages 17-29). Data on tuna oil has been available for over 30 years. Data on raw tuna oil used in the production of HiDHA® tuna oil from 1997 to 1999 indicates that only about 14 fatty acids make up the major portion of the composition of the oil and the relative fractions are:

- Saturates 29-30%
- Monounsaturates 23-25%
- Polyunsaturates 41-42%
- Ratio of EPA:DHA ranges from 0.25-0.26

The data indicate that the fatty acid content of raw tuna oil generally falls within the ranges of other marine oils with the distinction that the ratio of EPA to DHA is of the order of 0.25 while that for other fish oils is of the order of 0.65-2.5 and usually 1.0 or greater.

There is a very slight trace of *trans* fatty acids in the raw tuna oil amounting to less than 1.0% C16:1 *trans* accounting for more than half of the total *trans* fatty acids. Processing has very little effect on the total *trans* fatty acids in the oil.

Table 11 in the Expert Panel Report (Appendix I, page 28) demonstrates the minor variability between five batches of refined tuna oil in 1998 – 1999. This is summarized in Table 5.

Table 4: Comparison of 5 batches of refined tuna oil

Fatty acid	Batch EC101 33/11/99	Batch EG141 7/23/99	Batch EC181 4/9/99	Batch EE191 2/25/99	Batch DK091 12/7/98
Date	10.3.99	14.7.99	18.3.99	19.5.99	9.11.99
Saturates, %	29.36	32.52	28.41	27.62	28.00
Monounsaturates, %	22.01	23.38	22.79	23.31	23.33
Polyunsaturates, %	43.34	39.92	44.16	44.77	44.71
DHA, %	26.04	25.1	26.62	26.74	26.92
EPA, %	7.33	6.00	7.09	6.67	6.61
EPA/DHA	0.28	0.24	0.27	0.25	0.25

V) Environmental contaminants

The HiDHA® tuna oils contain extremely low levels of environmental contaminants because:

- The oil is deliberately sourced from specific tuna species harvested only in clean waters;
- The oil is extracted only from the body musculature; and
- The oil is "fail-safe" purified using advanced processing techniques.

The waters in the south and central regions of the South Pacific Ocean are relatively unpolluted hence oil extracted from the fish are much less contaminated with industrial and agrochemical residues than fish oil products from the more polluted waters of the Northern hemisphere.

No oil is extracted from the liver or any part of the viscera of the tuna fish further reducing the risk of contamination as these organs primarily accumulate fat-soluble environmental contaminants.

Following is a summary of processing steps used in the purification of HiDHA® tuna oil.

Table 5: Processing Steps for Purification of HiDHA® tuna oil

PROCESSING STEP	PURPOSE
Storage	Removal of insoluble impurities
Citric acid treatment	Chelation of pro-oxidant metal ions
Nitrogen purging	Stabilization of the raw tuna oil in preparation for shipping
Alkali refining process	Removal of free fatty acids, pigments, phospholipids, oil insoluble material, water-soluble material and trace metals
Bleaching process	Removal of pigments, oxidation products, trace metals, sulfur compounds and trace soaps
Winterization process	Removal of higher melting triglycerides leaving a clearer oil
Deodorization process	Removal of volatile components responsible for any odor or taste. Also decrease in free fatty acids, decomposition of any hydroperoxides present and some pigments to improve color.

The Clover tuna oil refining plant was designed specifically for refining tuna oil and uses unit processes that are standard in the edible oil industry. The factory is listed with the Australian Therapeutic Goods Administration and operates in accordance with pharmaceutical standard Good Manufacturing Practices ("GMPs"). The premises and the manufacturing processes have qualified for ISO 9002 and AQIS certification, and are operated to comply with a strict environmental protection code.

See Expert Panel Report (Appendix I, pages 29-37) for full details of analytical results.

3. Level of Use and Conditions of Use of HiDHA® tuna oil

Clover Corporation submits that HiDHA® tuna oils are reasonably expected to be safe for use in dietary supplements at up to one gram per day. There are no other conditions of use. Please note that this is the same level and conditions of use set forth in New Dietary Ingredient Report No. 17 for DHA-rich oil, now known as Marine Microalgae Oil..

4. HiDHA® tuna oil is Reasonably Expected to be Safe for Use in Dietary Supplements

Clover Corporation submits that the reasonable expectation of safety of tuna oil for use in dietary supplements is demonstrated through scientific procedures comparing the HiDHA® tuna oil to menhaden oil.

i) Product integrity

Controlled manufacturing procedures, strict product specifications and continuous product monitoring ensures that Clover's HiDHA® tuna oil products are consistently of a high standard and have a low threshold of contaminants.

ii) Product stability

HiDHA® tuna oil is sensitive to air, light and extended periods at elevated temperatures. The product may be stored for 2 years from date of manufacture in the unopened original drum, in cool (10-25° C), dry conditions (relative humidity less than 75%). After opening the original container, the oil will remain stable if thoroughly flushed with an inert gas (nitrogen, argon, etc) and resealed under inert gas. Only the following are suitable materials for equipment coming into contact with tuna oil: stainless steel, aluminum, glass, enamel or food-approved plastic.

Recent technological advances have led to the development of an expanded range of HiDHA® tuna oil products that offer greater flexibility of use in a stable form. Microencapsulation of tuna oil with permitted ingredients and additives has allowed the production of oxygen-sensitive tuna oils in a form which has good physical stability and enhanced resistance to oxidation.

iii) Intake exposure levels

HiDHA® tuna oil is intended for use as a replacement for menhaden oil in conventional foods under the conditions prescribed in 21 C.F.R. § 184.1472(a)(3) and for use in dietary supplements In affirming the GRAS status of menhaden oil, FDA established specific conditions for its use in traditional foods. The limiting factor in the menhaden oil GRAS affirmation was an increase in bleeding time, conservatively estimated to occur at intakes greater than 3 grams of EPA and DHA per person per day. The specific use limitations established by FDA in 21 C.F.R. § 184.1472(a)(3) to achieve commensurately limited exposure of EPA and DHA are listed in the Table below, and it is within these same limitations that HiDHA® tuna oils will be used in conventional foods. It is the position of Clover Corporation that these maximum levels of Menhaden oil for food use substantiate the safety of HiDHA® tuna oil for use in dietary supplements at levels of up to one gram per day.

Table 6: Maximum Level of use of Menhaden Oil

Category of food (21 C.F.R.)	**Maximum level of use in food (as served)**
Cookies, crackers, Sec. 170.3(n)(1)	5.0 percent
Breads, rolls (white & dark), Sec. 170.3(n)(1)	1.0 percent
Fruit pies, custard pies, Sec. 170.3(n)(1)	7.0 percent
Cakes, Sec. 170.3(n)(1)	10.0 percent
Cereals, Sec. 170.3(n)(4)	4.0 percent
Fats, oils, Sec. 170.3(n)(12), (not in infant formula)	20.0 percent
Yogurt, Sec. 170.3(n)(31)	4.0 percent
Cheese products, Sec. 170.3(n)(5)	5.0 percent

Frozen dairy products, Sec. 170.3(n)(20)	5.0 percent
Meat products, Sec. 170.3(n)(29)	10.0 percent
Egg products, Sec. 170.3(n)(11)	5.0 percent
Fish products, Sec. 170.3(n)(13)	20.0 percent
Condiments, Sec. 170.3(n)(8)	5.0 percent
Soup mixes, Sec. 170.3(n)(40)	3.0 percent
Snack foods, Sec. 170.3(n)(37)	5.0 percent
Nut products, Sec. 170.3(n)(32)	5.0 percent
Gravies, sauces, Sec. 170.3(n)(24)	5.0 percent

a) Historical intakes

Fish oils have been part of the human diet for millennia with communities living close to the coast continuing to consume regular and significant quantities of fish and therefore fish oils.

b) Conventional food use

It has been estimated that the average intake of EPA and DHA in the USA is about 0.1 g/day.

Unofficial recommended daily intakes of EPA and DHA are listed in Table 7. At this stage there are no official RDAs for omega-3 fatty acids in the USA or Australia.

Table 7: Unofficial recommended daily intakes of EPA and DHA

Organization	Recommendations for daily intakes
International Society for the Study of Fatty Acids and other Lipids	• 650 mg EPA and DHA for adults • minimum 220 mg EPA for adults • minimum 220 mg DHA for adults • For pregnant and lactating women ensure 300 mg DHA
British Nutrition Foundation	• 1145 mg EPA and DHA for women • 1430 mg EPA and DHA for men (Calculated from recommendation for a desirable population intake of 0.5% energy from very long chain omega-3s, which equates to about 8g EPA/DHA per week for women and 10g per week for men.)
American Heart Association	• 900 mg EPA and DHA for secondary cardiovascular disease prevention

c) Infant formula use

While this submission is a new dietary ingredient notification for HiDHA® tuna oil, it may of interest that Clover Corporation provides tuna oil to Nutricia Australia for Karicare First Infant Formula. The product, launched in February 1997 was presented as a unit of standard infant formula with 7 capsules of tuna oil and gamma-linolenic acid attached under the lid. From December 1998 onwards 0.2% DHA and 0.4% AA were encapsulated into the final product.

Since the end of 1997, 584,963 units of Karicare formula containing tuna oil have been distributed to retail pharmacy and grocery. Each unit provides one week's supply hence the equivalent of over 4 million daily serves of product have been supplied. In that time, 204 complaints in relation to the Karicare formula were registered with the manufacturer, Nutricia. (These complaints were not specifically related to the tuna oil component.) Products were retrieved where possible and tested by the manufacturer for a range of parameters. In every case the results have met with specifications for the tuna oil. (Appendix III).

iv) Safety studies

a) Biodisposition data (Absorption, Distribution, Metabolism and Excretion)

From Expert Panel Report (Appendix I, page 40):

> EPA and DHA are incorporated into circulating triglycerides in the same proportion that they appear in the dietary oil Their in vivo peroxidation is the same as that seen for oleate or linoleate). Initial hydrolysis of fish oils is lower than that seen for other fats. EPA and DHA show specificity for different phospholipids. Cholesterol esters become enriched with EPA but not with DHA. (Citations omitted.)
>
> Essentially, DHA is metabolized as are other fats although, being a bigger molecule, the reaction rates may be lower.

Recent studies by Yep Y.L. and colleagues at RMIT University, Melbourne determined the acute and chronic effects of human consumption of bread containing microencapsulated tuna oil. In the acute study the proportion of DHA and total omega-3 polyunsaturated fat were significantly increased in plasma triacylgycerol. In the chronic study, total omega-3 polyunsaturated fatty acids in the plasma phospholipid fraction were significantly increased. The authors concluded that low dose long chain omega-3 fatty acids consumed as microencapsulated fish oil-enriched bread, increased the long chain omega-3 fatty acids in plasma of human subjects (Appendix IV).

The Childhood Asthma Prevention Study is presently being conducted by the Children's Hospital at Westmead, Sydney, following evidence that increases in the prevalence of asthma during the 1980s and 1990s has been significant. The study will research the effects of a healthy diet with a favorable balance of omega-3 and omega-6 fatty acids and adequate antioxidants together with house dust mite avoidance on protection against the development of asthma or symptoms of wheeze in children who are prone to this illness. (Appendix V)

A principal component of the dietary intervention involves the use of HiDHA® tuna oil soft gel capsules. The capsules have been used by approximately half of the 600 children enrolled in the study. Over 5 years 1,056,000 individual capsules will be used in the study.

The plasma phospholipid levels of the babies in the study show that the HiDHA® tuna oil capsules have altered red cell plasma fatty acid membrane composition and are an effective measurable intervention for the purpose of investigating risk factors associated with the development of asthma.

The study is now in its third year with parents being asked to give their child one capsule per day. Some parents choose to give 2 capsules/day. To date, no children have had a negative effect from taking HiDHA® tuna oil capsules.

b) Preclinical data

From Expert Panel Report (Appendix 1, pages 40-41) discusses the preclinical toxicological evaluations of fish oil, including tuna oil. The Expert Panel Report notes that:

> The safety of EPA and DHA can be assumed from their long history of ingestion as part of the human diet. The FDA has critically evaluated available information on the safety of the n-3 fatty acids, EPA and DHA, and identified only three potential safety issues: prolongation of bleeding time, modification of glycemic control, and elevation of LDL cholesterol (US FDA 1993). These potential safety issues are discussed below. In 1997, following a critical evaluation of all information available, the FDA concluded that consumption of up to 3 grams/day of EPA and DHA in menhaden oil is generally recognized as safe (US FDA 1997). The safety of EPA and DHA at the current level of use in traditional foods has been recently supported by an extensive critical review by a task group formed by the Consumer Healthcare Products Association, the Council for Responsible Nutrition, and the National Fisheries Institute (Wright, 2000). This review updates the relevant scientific literature from 1993 until March 2000. It was submitted to FDA in April 2000 in response to the agency's request for scientific data and information concerning health claims for omega-3 (n-3) fatty acids. Of particular importance to this GRAS evaluation was the fact that newer evidence supports the view that DHA as opposed to EPA is safer with respect to earlier defined safety issues, and that no new adverse safety issues have been raised by the presence of an increased DHA:EPA ratio in fish oil.

c. Clinical data

The Expert Panel Report (Appendix I, pages 41- 45) discusses clinical data related to fish oils. This discussion demonstrates that tuna oil is reasonably expected to be safe for use as a dietary ingredient at levels of up to one gram per day.

Comparison of DHA-rich tuna oils to EPA-rich fish oil (Appendix VI).

In 1997 the CSIRO Division of Human Nutrition, Australia, compared DHA-rich tuna oil with commercial MaxEPA-type fish oil on acceptability and cardiovascular risk factors. The study participants were adult males, who consumed eight 1 g capsules per day for two 6-week periods. The results indicated that both supplements were well tolerated with fewer unfavorable comments about the DHA-rich tuna oil than the comparator. Both oils resulted in high circulating levels of omega-3 fatty acids. The results also demonstrated that DHA-rich tuna oil is as efficacious as EPA-rich fish oil in counteracting hypertriglyceridaemia and thrombotic tendency. Both supplements reduced serum thromboxane production (40%) and plasma triglycerides (26%), with a modest elevation of LDL cholesterol (6%). Neither oil supplement affected total or HDL cholesterol and there were no clinically relevant changes in blood pressure.

The study also examined effects on production of pro-inflammatory ytokines, viz. interleukin 1b (IL1b) and tumor necrosis factor (TNFa). There was no significant difference between the two supplements with an overall effect of 21% reduction in IL1b. There was no consistent effect on TNFa. The authors concluded that comparison to other studies indicates that both the dose and duration of treatment were adequate to demonstrate cytokine inhibition.

d. Regulatory status in Australia

In Australia, foods are regulated by the Australia New Zealand Food Authority through the Food Standards Code (Australia New Zealand Food Authority, 2000). Dietary supplements are regulated through the Therapeutic Goods Administration as are pharmaceuticals. The overlap between foods and drugs has been recognized by the authorities in Australia and is presently being addressed.

e. Australia New Zealand Food Authority

Fish oils, including tuna oil, are considered foods and as such, when included as an ingredient in a food (such as bread or yogurt), must be declared in the statement of ingredients on the label of that food. Standard 1.2.4 (Labelling of Ingredients) Clause 4 states:

"Ingredients must be declared in the statement of ingredients using

(a) the common name of the ingredient; or
(b) a name that describes the true nature of the ingredient; or
(c) where applicable, a generic name set out in the Table to this clause."

The Table to Clause 4 states that fats or oils must be qualified as to whether the source is animal or vegetable.

Standard 1.2.3 (Mandatory Warning and Advisory Statements and Declarations) Clause 4 states that fish and fish products must be declared on the label of a package of food.

As stated previously, claims relating to the omega-3 content of foods are also regulated. Standard 1.2.8 (Nutrition Information Requirements) (Div 3) Clause 13 (3) and (4) states:

(3) A nutrition claim must not be made in relation to the omega-3 fatty acid content of a food, unless the food satisfies the requirements of subclause (2) and contains no less than -

(a) 200 mg alpha-linolenic acid per serving; or
(b) 30 mg total eicosapentaenoic acid and docosahexaenoic acid per serving.

(4) A nutrition claim must not be made that a food is a 'good source' of omega-3 fatty acid or words of similar import, unless the food satisfies the requirements of subclause (2) and contains no less than 60 mg total eicosapentaenoic acid and docosahexaenoic acid per serving (Australia New Zealand Food Authority, 2000)

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Australian Therapeutic Goods Administration

The following approvals have been provided by the Therapeutic Goods Administration (TGA) in Australia.

Milkarra capsules produced by Clover Corporation and containing HiDHA® tuna oil are registered with the TGA as "MILKARRA capsule blister pack", ARTG Registration Number AUST R 55013 with commencement date of registration being 7 June 1996.

Gazette Notice 13, 3 April 1996 stated that the TGA gives notice that:

"the prohibited representation described in paragraph (a) below, being a representation that is necessary for the appropriate use of the therapeutic goods described in paragraph (b) below, may be included either on the label of the package of those goods or in information included in the package in which those goods are contained:

(a) a representation to the effect that the goods described in paragraph (b) below may assist normal neurological development in infants whose diets are deficient in long chain polyunsaturated fatty acids;
(b) MILKARRA capsule blister pack supplied as an over-the-counter drug by Clover Corporation Pty Ltd."

Conclusion

On the basis of the foregoing, Clover Corporation respectfully request that this new dietary ingredient notification for HiDHA® tuna oil be accepted for filing.

Anthony L. Young
Counsel for and Designee of Clover Corporation to Sign This New Dietary Ingredient Notification

PIPER MARBURY RUDNICK & WOLFE LLP

References

U.S. Food and Drug Administration (FDA). Food Labeling: Health Claims and Label Statements: Omega-3 Fatty Acids and Coronary Heart Disease. Federal Register. 58(3):2682-2738, January 6, 1993. [Copy not provided.]

U.S. Food and Drug Administration (FDA). Substances Affirmed as Generally Recognized as Safe: Menhaden Oil. Federal Register. 62(108):30751-30757, June 5, 1997. [Copy not provided.]

Wright, P.B. Comment submitted to FDA Docket No. 91N-0103 on behalf of a joint task group of the Consumer Healthcare Products Association (CHPA), the Council for Responsible Nutrition (CRN) and the National Fisheries Institute (NFI) in response to FDA's request for scientific data and information concerning health claims for omega-3 fatty acids (EPA and DHA), April 3, 2000, and appendices. [Copy provided on CD-rom.]